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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,043	02/20/2002	Markus Kostrzewa	B0032/7019	5152

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KUDIRKA & JOBSE, LLP
ONE STATE STREET
SUITE 1510
BOSTON, MA 02109

EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/079,043

Applicant(s)

Kostrzewa

Examiner

Arun Chakrabarti

Art Unit

1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 3, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*

Art Unit: 1634

DETAILED ACTION

Status of the Application

1. The amendment received on July 3, 2003 has been entered. Claims 1-23 have been newly amended. Claims 1-23 are pending and under consideration.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1634

3. Claims 1-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/079,271. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 of copending Application No. 10/079,271 encompass the cleaving of the photocleavable linker by UV light radiation of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 18, and 21-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/079,271 in view of Van Ness et al. (PCT International Publication Number WO 97/27325) (July 31, 1997).

This is a provisional obviousness-type double patenting rejection.

5. Claims 1-9 of copending Application No. 10/079,271 teach the instant claims 1-6 as described above.

Claims 1-9 of copending Application No. 10/079,271 do not teach a method, wherein ionization in the mass-spectrometric mass determination is achieved by using matrix-assisted laser desorption and ionization

Van Ness et al teaches a method, wherein ionization in the mass-spectrometric mass determination is achieved by using matrix-assisted laser desorption and ionization (Example 13).

Art Unit: 1634

Claims 1-9 of copending Application No. 10/079,271 do not teach a method, wherein the 5' position of the extension primer is biotinylated and can inherently be bonded to streptavidin molecules which may be fixed to a surface for the purpose of purging all the components of the reaction fluid which was required for the extension.

Van Ness et al teaches a method, wherein the 5' position of the extension primer is biotinylated and can inherently be bonded to streptavidin molecules which may be fixed to a surface for the purpose of purging all the components of the reaction fluid which was required for the extension (Example 11).

Claims 1-9 of copending Application No. 10/079,271 do not teach a method, wherein the streptavidin may be bonded to the surface of a sample support which is also used for further mass-spectrometric analysis.

Van Ness et al teaches a method, wherein the streptavidin may be bonded to the surface of a sample support which is also used for further mass-spectrometric analysis (Example 11).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein ionization in the mass-spectrometric mass determination is achieved by using matrix-assisted laser desorption and ionization of Van Ness et al. in the method of claims 1-9 of copending Application No. 10/079,271, since Van Ness et al. states, "More importantly, the example demonstrates that multiple tags can be detected simultaneously by a spectroscopic method (Page 106, lines 2-4)." An ordinary practitioner would have been motivated to combine and substitute the method,

Art Unit: 1634

wherein ionization in the mass-spectrometric mass determination is achieved by using matrix-assisted laser desorption and ionization of Van Ness et al. in the method of claims 1-9 of copending Application No. 10/079,271, in order to achieve the express advantages noted by Van Ness et al. of a procedure which demonstrates that multiple tags can be detected simultaneously by a spectroscopic method.

6. Claims 7-17, and 19-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/079,271 in view of Sauer et al. (Nucleic Acids Research, (2000), Vol. 28 (5), pages e13 I-viii).

Claims 1-9 of copending Application No. 10/079,271 teach the instant claims 1-6 as described above.

Claims 1-9 of copending Application No. 10/079,271 do not teach a method, wherein the internucleotide cyanoethyl phosphite bond of the primer nucleotides between the linker and the 3' position are sulphurized forming phosphorothioate nucleotides, and wherein the phosphorothioate nucleotides are alkylated before analysis by mass spectrometry.

Sauer et al. teach the method, wherein the internucleotide cyanoethyl phosphite bond of the primer nucleotides between the linker and the 3' position are sulphurized forming phosphorothioate nucleotides, and wherein the phosphorothioate nucleotides are alkylated before analysis by mass spectrometry (MATERIALS and METHODS Section, alkylation reaction and Figure 1).

Art Unit: 1634

Claims 1-9 of copending Application No. 10/079,271 do not teach a method, wherein the alpha-thiodideoxynucleoside triphosphates are used as the nucleoside triphosphate derivative terminators.

Sauer et al. teach the method, wherein the alpha-thiodideoxynucleoside triphosphates are used as the nucleoside triphosphate derivative terminators (MATERIALS and METHODS Section, Primer extension reaction).

Claims 1-9 of copending Application No. 10/079,271 do not teach a method, wherein the alpha-thionucleoside triphosphate derivative terminators carries a chemical group with a positive charge in addition located on the second, third or fourth nucleobase counting from the 3' position.

Sauer et al. teach the method, wherein the alpha-thionucleoside triphosphate derivative terminators carries a chemical group with a positive charge in addition located on the second, third or fourth nucleobase counting from the 3' position (MATERIALS and METHODS Section, first and second paragraph).

Claims 1-9 of copending Application No. 10/079,271 do not teach a method, wherein the primer for the primer extension carries an anchor amino group before the analysis by mass spectrometry is carried out.

Sauer et al. teach the method, wherein the primer for the primer extension carries an anchor amino group before the analysis by mass spectrometry is carried out (MATERIALS and METHODS Section, first and second paragraph).

Art Unit: 1634

Claims 1-9 of copending Application No. 10/079,271 do not teach a method, wherein a matrix alpha-cyano-4-hydroxycinnamic acid methyl ester is used which does not contribute to the transfer of charge to the DNA products being measured.

Sauer et al. teach the method, wherein a matrix alpha-cyano-4-hydroxycinnamic acid methyl ester is used which does not contribute to the transfer of charge to the DNA products being measured (MATERIALS and METHODS Section, Sample preparation for MALDI analysis subsection).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein a matrix alpha-cyano-4-hydroxycinnamic acid methyl ester is used which does not contribute to the transfer of charge to the DNA products being measured and specific chemically modified primers of Sauer et al. in the method of claims 1-9 of copending Application No. 10/079,271, since Sauer et al. states, "The procedure is useful for high throughput genotyping as it is required for gene identification and pharmacogenomics where large number of DNA samples have to be analyzed (Abstract, page e13i, column 2, lines 3-6)." An ordinary practitioner would have been motivated to combine and substitute the method, wherein a matrix alpha-cyano-4-hydroxycinnamic acid methyl ester is used which does not contribute to the transfer of charge to the DNA products being measured and specific chemically modified primers of Sauer et al. in the method of claims 1-9 of copending Application No. 10/079,271, in order to achieve the express advantages noted by Sauer et al. of a

Art Unit: 1634

procedure useful for high throughput genotyping as it is required for gene identification and pharmacogenomics where large number of DNA samples have to be analyzed.

Response to Amendment

7. In response to amendment, 112(second paragraph) rejection to claims 1-23, objection to claims 22 and 23, 102 (b) and 103(a) rejections have been withdrawn. However, provisional obviousness-type double patenting rejection with respect to claims 1-6 has been properly maintained as this rejection has not been rebutted. New ground of provisional obviousness-type double patenting rejection with respect to claims 7-23 have been included.

Response to Arguments

8. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO


Art Unit: 1634

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, who can be reached on (703) 308-1119. Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti
Patent Examiner
Art Unit 1634

July 28, 2003


GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600